SYSTEM FOR THE PREDICTION, RAPID DETECTION, WARNING, PREVENTION, OR CONTROL OF CHANGES IN ACTIVITY STATES IN THE BRAIN OF A SUBJECT

RELATED APPLICATIONS

This application claims priority under 35 U.S.C. § 119(e) of Provisional Application Serial No. 60/010,477, filed Jan. 23, 1996 entitled SYSTEM FOR THE PREDICTION, RAPID DETECTION, WARNING, PREVENTION, OR CONTROL OF CHANGES IN ACTIVITY STATES IN THE BRAIN OF A SUBJECT.

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

MICROFICHE APPENDIX

A microfiche appendix as Appendix 1 containing a source code of a computer program useful in accordance with the present invention is appended hereto as 1 sheet of microfiche containing 20 frames.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the field of neuroscience for analyzing signals representative of a subject's brain activity including signals indicative or predictive of epileptic seizures. More particularly, the invention concerns the automated analysis of brain activity signals to detect an activity state and transitions between states, and to detect precursors predictive of a change in the subject's activity state to a different state.

The invention is based on ideas and research in the fields of mathematics, neurology, statistics and engineering which enable the real-time analysis of biologic signals such as the electro-encephalogram (EEG) or electro-corticogram (ECoG), by the simultaneous execution of multiple methods. In the preferred embodiment, these signals are rapidly, accurately, and automatically analyzed in order to:

1) Detect and signal the occurrence of an epileptic seizure in real time (or contemporaneously with the arrival of the signal at the processor/device),
2) To predict behavioral changes typically associated with seizures,
3) To predict seizures by detecting precursors to the onset of the electrographic or clinical components of a seizure,
4) To detect and further analyze epileptiform discharges (spikes), and
5) To download the detection or prediction outputs to devices for warning, or therapeutic interventions or the storage of data.

2. Description of the Prior Art

Humans and animals have several normal states of behavior such as wakefulness and sleep, as well as multiple sub-states such as attentive wakefulness and REM sleep. Abnormal states include reversible states such as seizures and progressive states such as dementia.

Epilepsy, a disabling disease, affects 1–2% of the American and industrialized world's population, and up to 10% of people in under-developed countries. Electroencephalography is the single most important ancillary test in the investigation of this disease. EEG's are recorded continuously for

hours to days in an increasing number of cases with unclear diagnosis or poor response to adequate medical treatment. The amount of EEG data for analysis is extremely large (e.g., 64 channels of data at 240 Hz gives 1.3 billion data points/24 hr or 2.6 Gigabytes/day) and consists of complex waveforms with infinite variations.

Visual analysis of these signals remains (exclusive of this invention) the "gold standard" but it is impracticable for continuous EEG interpretation as this is the most time-consuming part of any electrodiagnostic test and requires special training and skills which make this procedure expensive and thus of limited access and use. Valuable EEG data is often discarded unexamined. The length of recording is unnecessarily prolonged in a specially equipped hospital suite until patients have several seizures. If the patient is unaware of the seizures, a common occurrence, then a nurse or relative must observe and document the occurrence of these changes. As seizures are brief and previously considered unpredictable, the need for continuous observation becomes imperative, adding to the cost in a non-effective manner.

Present methods of seizure detection are not only expensive, but rely on poorly discriminating methods, increasing the review time and nursing assistance because of the large number of false positives, and increasing the length of hospitalization through the false negatives. Furthermore, these methods often "detect" the seizure well after its onset or even its end, when prevention or abatement of the seizure is not possible or irrelevant.

The inability to process data in real time has thwarted the scientific and clinical development of the fields of epilepsy and electroencephalography. Cardiology has developed into a clinical science largely based on the power of electrocardiography to analyze the heart's electrical activity in a rapid and accurate manner. This has resulted in pacemakers, implanted defibrilators, and other devices which have saved thousands of individuals from premature death. The comparison between cardiology/EKG and epilepsy/EEG must take into account the fact that the electrical brain signals are far more complex than those originating from the heart. This explains in large part the developmental lag between these two disciplines.

Electrical brain signals, because of their spatial and temporal characteristics such as non-stationarity, have resisted accurate real-time automatic manipulation. The prior art methods presently used to characterize these states are severely limited. For example, the prior art consists of a long history of failed attempts to identify changes in EEG during certain behavioral states or tasks and to discern epi-phenomenology from phenomenology, a distinction that would help answer questions of fundamental importance. Other limitations include the inability to determine whether spikes are a static marker of epilepsy, or whether they are dynamically related to seizure generation.

Present methods of automatic EEG analysis have many major limitations which render them virtually useless for widespread, safe and effective clinical applications. These limitations include:

1) Lack of speed. The time it takes most methods to analyze the input signals and produce an output which detects or predicts a state change is too great for use in warning, intervention, or prevention of epileptic seizures and other abnormal brain states.
2) Lack of accuracy. Prior art methods have a large number of false positives (incorrectly identifying non-seizure activity as a seizure) and false negatives (failure to identify a true seizure), increasing the technical and financial burden.